

REMARKS

Applicants respectfully request reconsideration of the patent application.

I. Title

The title of the invention has been amended in view of a change in nomenclature for the nuclear receptors of the present invention. See *Schering Corp v. Amgen Inc.*, 55 USPQ2nd 1650, 1654 (CAFC 2004). Applicants submit with the Information Disclosure Statement filed herewith the paper *Nuclear Receptors Nomenclature Committee* (1999), 97: 161-163 in support of the title change.

II. Status of Claims

Claims 1-2, 13, 16-17, 51, 53, and 81-89 are currently pending in the application.

New claims 81-89 have been added by this amendment to better define Applicants invention without the introduction of new matter. Support for the new claims is provided in the specification and the original claims. Support for claim 86, for example, is found in SE9703745-1 at page 4, lines 15-21.

Applicants acknowledge that claims 2, 51 and 53 are allowed.

Claims 14, 52, and 54-80 have been cancelled without traverse.

Applicants reserve the right to pursue the subject matter of any withdrawn or cancelled claims in one or more continuing applications.

III. Double Patenting

The Examiner noted that should Claims 15-17, 56-58, and 62 be found allowable, Claims 64-73 and 78-80 would be objected to under 37 CFR §1.75 as being a substantial duplicate thereof. Applicants have mooted this potential objection by canceling claims 64-73 and 78-80 without traverse.

IV. Claim Rejections

1. Claims 16-17, 54-55, 71-72 and 79-80 were rejected under 35 USC §112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to gaps between steps. Applicants respectfully traverse this rejection. Claim 16 has been amended to moot this objection. Claims 54-55, 71-72 and 79-80 have been cancelled without traverse. Applicants respectfully request reconsideration of Claims 16-17.

2. Claims 14, 52, and 69 were rejected under 35 USC §112, first paragraph, on the basis of that specification, while enabling for isolated cells transfected or transformed with an expression vector does not reasonably provide enablement for an isolated cell comprising nucleic acid which is not contained in the vector. Applicants respectfully traverse this rejection. Claims 14, 52, and 69 have been cancelled without traverse and thus moot this rejection.

3. Claims 16-17, 54-55, 71-72 and 79-80 were rejected under 35 USC §112, first paragraph, on the basis that the specification, while being enabling for a process for recombinant production of a polypeptide comprising culturing an isolated host cell comprising the expression vector comprising the desired nucleic acid and producing the peptide, but does not reasonably provide enablement for the claimed process which only expresses the nucleic acid in the host cell. Applicants respectfully traverse this rejection. Claim 16 has been amended to moot this rejection. Support for the amendment is found at page 5, lines 15-18 and page 8, lines 9-14 of SE9703745-1. Claims 54-55, 71-72 and 79-80 have been cancelled without traverse. Applicants respectfully request reconsideration of Claims 16-17.

4. The Examiner has acknowledged Applicants' claim for priority under 35 USC §120. Priority is claimed for Swedish Patent Applications SE 9703745-1 filed on October 14, 1997 and SE 9801148-9 filed on March 31, 1998 and US Provisional Patent Application No. 60/067,373 filed on December 3, 1997. The Examiner asserts that the applications on which priority is claimed fail to provide adequate support under 35 USC §112 for claims 1-2, 13-17, 51-58, 60 and 62-80 of

the present application. Two separate grounds for objection of the claim for priority are noted by the Examiner and each of these is responded to in turn.

Before addressing the Examiner's objections, it is submitted that the determination of priority of invention involves a complex body of procedural and substantive law, applied in a first instance in administrative proceedings. In accordance with 35 USC §135(a). See *Hyatt v. Boone*, 47 USPQ2d 1128, 1129 (CA FC 1998). The Board of Patent Appeals and Interferences shall determine questions of priority of inventions and may determine questions of patentability.

Thus, the Examiner's objections to priority are understood by Applicants only (emphasis added) as rejections to the specified claims under 35 USC §112, first paragraph, Applicants provide the following remarks to those presumed rejections.

The Examiner first argues that claims 1, 13-17, 56-58, 60, 63-65, 68-75 and 78-80 do not receive priority of the specific claim limitations drawn to the specific amino acid residue numbers "39-115 or 141-434 of SEQ ID NO:2". The Examiner argues that the only support for the specific amino acid residue numbers can be found in the current application in Fig. 12, which figure is not present in the parent applications. Applicants respectfully traverse this first presumed written description rejection.

Applicants submit that any specific amino acid residue numbers referred to in Fig. 12 relate to a comparison of the percent similarity of amino acid residues within those regions to comparable regions of amino acid residues of the known genes XOR-6, hVDR, CAR-1 and CAR-2. The information provided in Fig. 12 is also described in the specification at page 8, lines 1-23. This data provides support of Applicants' finding that the newly identified receptors are members of the nuclear receptor super-gene family based on comparison with the other members noted in Fig. 12. Applicants further note that SE 9703745-1 at page 3, lines 8 to page 4, lines 3 provides that the newly identified nuclear receptors incorporate a DNA-binding domain and a ligand-binding domain. The percent sequence identity of the encoded polypeptide is compared to DNA-binding domain and ligand-binding domain of two other known nuclear receptors in the patent application, specifically hCDR and xONR-1. The receptor xONR1 is noted to be the same as the receptor XOR-6 being a nuclear receptor isolated from *Xenopus laevis*. ONR1 has also been recently

classified as a NR1I2 receptor. Further, it is submitted that one of skill in the art could readily identify based on the information provided the Applicants' first priority application the DNA-binding domain and/or the ligand-binding domain regions for the newly identified receptors of the present application based on the use of these sequence alignments. Without waving any rights of Applicants to pursue claims directed to specific amino acid residues of the claimed receptors, Applicants have amended the claims to moot this written description rejection. Reconsideration of the claims is respectfully requested.

The Examiner has further argued that Claims 1-2, 13-17, 51-58, 60 and 62-80 receive priority for the utility and enablement of the receptor for the foreign priority only for SE 9801148-9 because the prior parent applications 60/067,373 and SE 9703745-1 do not disclose the function of the orphan receptor. Applicants respectfully traverse this second presumed written description rejection.

Applicants have previously replied to a rejection of the claims under 35 USC §101 and 35 USC §112, first paragraph, relating to the utility of the receptors disclosed in the present application. See Applicants' response mailed January 8, 2003. Applicants' arguments presented in that response fully respond to the present rejection.

Further, it is respectfully submitted that Applicants' priority application SE 9703745-1 fully complies with the written description requirement with respect to the claimed nuclear receptors. The test for determining compliance with the written description requirement is whether the disclosure in the application as originally filed reasonably conveys to the artisan that the inventors had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. See *In re Kaslow and Uniform Product Code Council, Inc.*, 217 USPQ 1089, 1096 (CA FC 1983). In addition, Applicant's specification need not describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and even extrapolate beyond the disclosed embodiments, depending on the predictability of the art. See *Chiron Corp. v. Genentech Inc.*, 70 USPQ2D 1321, 1325 (CA FC 2004). With respect to the presently claimed divergent polynucleotides, Applicants submit

that the state of the art has developed that an amino acid sequence of a protein may put one in possession of a genus of DNA sequences encoding it. See *In re Wallach*, 71 USPQ2d 1939, 1942 (CA FC 2004). Applicants respectfully request reconsideration of the claims.


5. Claims 1, 13-17, 56-58, 60, 63-65, 68-75 and 78-80 were rejected under 35 USC §102(e) as anticipated by Adams, et al., (US 6,756,491). Applicants respectfully traverse this rejection.

It is respectfully submitted that prima facie anticipation rejection under 35 USC§102(e) has been properly established. The earliest filing date noted on the cover of the Evans, et al. patent (US 6,756,491) is January 9, 1998, which postdates Applicants' earliest priority date for SE 9703745-1 filed October 14, 1997. Fig. 4 of SE9703745-1 provides the disclosure of SEQ ID NO:2. Claims 14-15, 56-58, 60, 63-65, 68-75 and 78-80 have been cancelled without traverse. Applicants respectfully request reconsideration of the claims 1, 13 and 16-17.

Conclusion

Applicants submit that all the grounds for rejection of the pending claims have now been overcome and that all the claims are now in condition for allowance, which action is respectfully requested. The Examiner is encouraged to contact the Applicants' undersigned attorney by telephone as needed to advance this application.

Respectfully submitted,



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